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EXAMINER

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/806,531
Filing Date: March 23, 2004
Appellant(s): FEYGIN ET AL.

Wayne S. Breyer
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 3/31/2009 appealing from the Office action mailed 11/12/2008.

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(1) Real Party in Interest

The real party in interest is Laerdal.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

Cunningham et al. (US 6,470,302)

Rosenberg et al. (US 5,821,920)

Grayzel (US 4,850,960)

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(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1, 4-6, 8, 10, 12, 15-17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cunningham et al. (US 6,470,302 B1) in view of Rosenberg et al. (US 5,821,920) and further in view of Grayzel (US 4,850,960).

Re claim 1, Cunningham teaches an apparatus comprising:

a needle/catheter module (Cunningham, col 7, lines 5-20: interface device (30)),

wherein the needle/catheter module comprising:

a needle (Cunningham, col 7, line 9);

a catheter, wherein said catheter receives said needle (Cunningham, col 7, lines 43-53: the catheter hub includes cross-sectional dimensions greater than the cross-sectional dimensions of needle shaft to receive the needle shaft in the catheter hub);

Cunningham does not explicitly teach of a needle or catheter comprising a bevel; a sensor, wherein said sensor senses orientation of the bevel; and a pseudo skin, wherein said pseudo skin comprises an opening for receiving said needle and said catheter. Cunningham teaches of having sensors in sensing the position of the needle / catheter, a computer simulated surface and subsurface anatomy of the human skin (col 7, lines 5-8).

Rosenberg teaches of a catheter comprises a bevel (Rosenberg, col 5, lines 10-14: preferably the catheter is modified such that the end of the tool (such as any cutting edges are removed, leaving only the handle and the shaft)); Rosenberg further teaches a sensor, wherein said sensor senses an orientation of the bevel (Rosenberg, col 8, lines 13-15: rotation transducer is rotatably coupled to object receiving portion to determine the rotational motion of elongated flexible object

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(catheter) - by sensing the rotational motion of the elongated flexible object the sensor also determines the orientation of the bevel, as bevel orientation are directly correlated to the rotation of the catheter);

and a pseudo skin (Rosenberg, col 4, lines 64-67: the barrier is used to represent portion of the skin covering the body of a patient); wherein said pseudo skin comprises an opening for receiving said needle and said catheter (Rosenberg, col 6, lines 8-22: apparatus includes an object receiving portion into which an elongated flexible object, such as a catheter, is introduced through aperture). It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention for Cunningham to have a needle, catheter, with a bevel, a sensor to sense the orientation of the bevel and a pseudo skin having an opening for receiving said needle and needle catheter assembly. A needle (hypodermic needle in medical term) is commonly used with a syringe or catheter to inject or extract substance into or from the human. The needle, the sharp edge of the needle, is much more than just a blunt hollow tube. The sharp, pointed tip of the needle is what allows the needle to puncture the skin. Therefore a bevel is essential in a needle, needle catheter assembly. The many different factors that determines the skill level of the trainee in performing a vascular-access procedure includes the accurate placement of the needle under the skin into the vein or inside the intradermal tissue, which directly correlates with sensing the orientation of the bevel of the needle in the insertion. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have a sensor sensing the orientation of the bevel of the needle for the assessment of the student during the simulation to realistically and accurately determine the orientation of the needle / catheter bevel. It would also have been obvious for one of ordinary skill in the art to have a pseudo skin comprising an opening for

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receiving said needle and catheter to provide a cosmetic look-alike to create a realistic simulation of needle/catheter insertion. Cunningham and Rosenberg are also in the same field of endeavor of catheter/needle simulations.

Additionally Grayzel teaches of a catheter with a bevel (see fig 1 of the drawing), the catheter has indication means in the form of a longitudinal stripe as in fig 2, in addition, indicating means disposed at approximately 90 degree angles at either side of the central indicating means. These are shown as a series of circles and a series of squares... the physician-surgeon using the introducing catheter will always be aware of the position of the plane of the bevel (orientation of the bevel) and therefore where the tip of the bevel is with relation to the vascular puncture hole (col 9, lines 1-15); It would also have been prima facie obvious to one of ordinary skill in the art at the time of the invention to utilize the indicating means in sensing the orientation of the bevel to easily gauge the correct placement of the needle under the skin by the student, as the indicating means provides an indication of the orientation of the bevel even after the needle insertion because the indication would still be visible. Cunningham and Grayzel are also in the same field of endeavor of inserting catheter/needle.

Re claim 4, Rosenberg teaches a receiver for receiving at least one of said needle and said catheter, wherein said receiver is disposed underneath said pseudo skin and covered by said pseudo skin (Rosenberg, col 4, lines 62-68 and col 5, lines 1-3: the human/interface apparatus includes a barrier and a central line through which the catheter is inserted into the body. The barrier is used to represent portion of the skin covering the body of a patient... central line is

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inserted into the body of the patient to provide an entry and removal point of The body of the patient for the catheter). It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to have a receiver disposed underneath said pseudo skin to receive the catheter/needle to realistically simulate a life-like representation of a body or body portion by providing realistic feedback to the student, and a pseudo skin in providing a realistic cosmetic representation of the skin.

Re claim 5, Cunningham, Rosenberg and Grayzel do not explicitly teach that the sensor is physically coupled to said needle. Instead the sensor is located within the housing unit or the simulator.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to place the sensor coupled to the needle, because Appellant has not disclosed that by coupling the sensor to the needle provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected appellant's invention, to perform equally well with either the sensor attached to the needle/catheter or to the housing unit because both would perform the same function of measuring the orientation of the needle and the catheter / bevel.

Therefore, it would have been prima facie obvious to modify Cunningham, Rosenberg, and Grayzel because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Rosenberg, Cunningham and Grayzel.

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Re claim 6, Rosenberg teaches data processing system that receives a signal that is indicative of said orientation of said bevel (by sensing the rotational orientation of the needle/catheter).

Re claim 8, Rosenberg teaches a housing, wherein said receiver is disposed within said housing, and wherein said pseudo skin is substantially co-planar with a surface of said housing (Rosenberg, col 4, lines 62-68).

Re claim 10, Cunningham teaches the use of a force feedback assembly, wherein at least one of said needle and said catheter detachably couples to said force-feedback assembly (col 7, lines 35-67: catheter unit assembly includes a base... a catheter needle assembly and a shaft for receiving catheter needle assembly. The catheter needle assembly includes needle assembly and a catheter hub... the catheter hub includes cross-sectional dimensions greater than the cross-sectional dimensions of needle shaft to receive the needle shaft in the catheter hub; col 10, lines 3-30: a force feedback unit is disposed within housing to provide feedback force to the catheter needle assembly for a realistic simulation. The force feedback unit is coupled to shaft via a tension member to impede shaft motion based on control signals received from computer system via communications interface – the shaft is used to receive catheter needle assembly, and the force feedback unit is coupled to the shaft, therefore the catheter needle assembly is detachably coupled to the force-feedback assembly).

Re claim 12, Cunningham teaches an apparatus comprising:

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An end effector comprises a needle catheter module, where said needle catheter module includes: a needle; a catheter, where said catheter receives said needle, (Cunningham, col 7, lines 5-20: interface device (30)),

a needle (Cunningham, col 7, line 9);

a catheter, wherein said catheter receives said needle (Cunningham, col 7, lines 43-53: the catheter hub includes cross-sectional dimensions greater than the cross-sectional dimensions of needle shaft to receive the needle shaft in the catheter hub);

Cunningham does not explicitly disclose of have the pseudo skin covering the force-feedback unit. Cunningham teaches of a computer simulated surface and subsurface anatomy of human skin (col 7, lines 5-8). Rosenberg teaches the use of pseudo skin covering the force-feedback unit (Rosenberg, col 4, lines 64-67);

Cunningham teaches of a force-feedback assembly (col 7, lines 18-20), but does not explicitly teach that the force-feedback assembly is disposed beneath and is at least partially covered by said pseudo skin, Rosenberg teaches of having a force-feedback assembly, and the force-feedback assembly is disposed beneath and is at least partially covered by said pseudo skin (Rosenberg, col 13, lines 53-67: output transducers are used to respond to electrical signals developed by the computer to impart a force upon the shaft of the catheter);

Cunningham teaches of a end effector reversibly coupled to said force-feedback assembly (Cunningham, col 10, lines 3-10 – a force feedback unit is coupled to shaft via tension member to impede shaft motion based on control signals – such impede motion would apply to both insertion and withdrawn of the needle / catheter); Cunningham does not explicitly teach of the end effector passes through pseudo skin. Rosenberg teaches an end effector, where said end

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effector passes through said pseudo skin to reversibly couple to said force-feedback assembly (Rosenberg, col 4, lines 64-67: pseudo skin; col 13, lines 53-67, the force acted upon the actuator making it hard for the user to push the shaft further would also have a equal force for the user to pull the shaft out - reverse coupling);

Cunningham does not teach of a needle / catheter having a bevel, and a sensor to sense the orientation of the bevel. Rosenberg teaches of a catheter comprise a bevel (Rosenberg, col 5, lines 10-14: preferably the catheter is modified such that the end of the tool (such as any cutting edges are removed, leaving only the handle and the shaft)), a sensor, wherein said sensor senses an orientation of the bevel (Rosenberg, col 8, lines 13-15: rotation transducer is rotatably coupled to object receiving portion to determine the rotational motion of elongated flexible object (catheter) - by sensing the rotational motion of the elongated flexible object the sensor also determines the orientation of the bevel, as bevel orientation are directly correlated to the rotation of the catheter);

It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention for Cunningham to have a needle, catheter, with a bevel, a sensor to sense the orientation of the bevel and a pseudo skin having an opening for receiving said needle and needle catheter assembly. A needle (hypodermic needle in medical term) is commonly used with a syringe or catheter to inject or extract substance into or from the human. The needle, the sharp edge of the needle, is much more than just a blunt hollow tube. The sharp, pointed tip of the needle is what allows the needle to puncture the skin. Therefore a bevel is essential in a needle, needle catheter assembly. The many different factors that determines the skill level of the trainee in performing a vascular-access procedure includes the accurate placement of the needle under

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the skin into the vein or inside the intradermal tissue, which directly correlates with sensing the orientation of the bevel of the needle in the insertion. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have a sensor sensing the orientation of the bevel of the needle for the assessment of the student during the simulation to realistically and accurately determine the orientation of the needle / catheter bevel. It would also have been obvious for one of ordinary skill in the art to have a pseudo skin partially cover the force-feedback assembly to provide a cosmetic look-alike to create a realistic simulation of needle/catheter insertion simulation of the human skin. Cunningham and Rosenberg are also in the same field of endeavor of catheter/needle simulations.

Additionally Grayzel teaches of a catheter with a bevel (see fig 1 of the drawing), the catheter has indication means in the form of a longitudinal stripe as in fig 2, in addition, indicating means disposed at approximately 90 degree angles at either side of the central indicating means. These are shown as a series of circles and a series of squares... the physician-surgeon using the introducing catheter will always be aware of the position of the plane of the bevel (orientation of the bevel) and therefore where the tip of the bevel is with relation to the vascular puncture hole (col 9, lines 1-15); It would also have been prima facie obvious to one of ordinary skill in the art at the time of the invention to utilize the indicating means in sensing the orientation of the bevel to easily gauge the correct placement of the needle under the skin by the student, as the indicating means provides an indication of the orientation of the bevel even after the needle insertion because the indication would still be visible. Cunningham and Grayzel are also in the same field of endeavor of inserting catheter/needle.

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Re claim 15, Cunningham teaches a force-feedback assembly receives a control signal from said data processing system (Cunningham, col 10, lines 3-31: the force feedback unit is coupled to shaft via a tension member to impede shaft motion based on control signals received from computer system via communications interface).

Re claims 16, Cunningham teaches signals that are indicative of a position of said end effector are transmitted to said data processing system (Cunningham, col 9, line 55- col 10, line 3: the translational motion of the proximal end of transverse bar enables the transverse bar distal end to rotate coupling shaft, whereby potentiometer measure the coupling shaft rotation, thereby indicating the angle of pitch of shaft. A yaw potentiometer is disposed below and attached ... measures the yaw portion of catheter needle assembly. The communications interface receives the signal from potentiometers indicating catheter needle assembly manipulation (pitch and yaw) and transmit the signals to computer system for processing).

Re claim 17, Cunningham teaches a housing, a force-feedback assembly disposed within the housing (col 7, lines 20-25), Cunningham does not teach that the pseudo skin is substantially co-extensive with a surface of the housing. Rosenberg teaches a housing ,wherein said force-feedback assembly is disposed within said housing and wherein said pseudo skin is substantially co-extensive with a surface of housing (Rosenberg, col 4, lines 62-67 and col 13, lines 53-67). It would have been obvious to one of ordinary skill in the art at the time of the invention to have the pseudo skin substantially co-extensive with a surface of the housing to provide a cosmetic

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look-alike to create a realistic simulation of the catheter needle simulation representation of the human skin.

Re claim 19, Rosenberg teaches data processing system, wherein said data processing system receives a signal that is indicative of said orientation of said bevel (Rosenberg, col 8, lines 13-15: rotation transducer is rotatably coupled to object receiving portion to determine the rotational motion of elongated flexible object (catheter) - by sensing the rotational motion of the elongated flexible object the sensor also determines the orientation of the bevel, as bevel orientation are directly correlated to the rotation of the catheter); Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have a sensor sensing the orientation of the bevel of the needle for the assessment of the student during the simulation to realistically and accurately determine the orientation of the needle / catheter bevel.

(10) Response to Argument

The appellant's arguments are treated according to the format filed.

Grounds of rejection as it pertains to independent claim 1

Re appellant's arguments on pages 13-16, pertaining to claim 1, the appellant's arguments toward claim 1 appears to encompass the invention as a whole instead of specific limitations from the claim. The appellant is reminded that although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The specifics are explained below:

The appellant's first argument (page 13 - page 14, line 20) presented general allegations of having previously known the competitor's (Cunningham) invention, having scrutinized, identified its shortcomings and improved upon it. Namely asserting that the catheter needle assembly by Cunningham is permanently coupled to the force-feedback system (i.e. the receiver or the shaft) (starting at page 13, lines 23). The appellant asserts that as discussed in appellant's specification, it is not atypical for an end effector to be permanently coupled to its force-feedback system in a haptics device due to the difficulty of engineering a system that enables them to be decoupled. The inability to decouple the end effector from the force-feedback system is very undesirable, to truly mimic most "actual" systems, de-coupling is necessary.

The examiner respectfully disagrees with the argument as appellant's argument amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the reference.

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Claim 1 recites:

An apparatus comprising:

a needle/catheter module, wherein the needle/catheter module comprises:

a needle;

a catheter, wherein said catheter receives said needle, and wherein at least one of said needle or said catheter comprise a bevel;

a sensor, wherein said sensor senses an orientation the bevel; and

pseudo skin, wherein said pseudo skin comprises an opening for receiving said needle and said catheter.

Contrary to appellant's argument the claim does not recite the limitation of inserting the module during a simulated vascular-access procedure, and decoupling (withdrawing) of the end effector from the force-feedback system at the end of the training. The claim makes no tie between the sensor for sensing an orientation of the bevel to the insertion and extraction of the end effector. There are no further recitations which state that the coupling and the decoupling of the needle / catheter from the shaft or force-feedback system. As the features of coupling and decoupling of the needle / catheter from the force-feedback system not required by the pending claim, appellant's argument such as required by the prior art are consider moot.

The appellant asserts that Cunningham does not teach of a bevel, therefore the orientation of the bevel; and the pseudo skin having an opening for receiving the catheter and needle on page 14, lines 21 – page 15, line 3:

In any case, since there is no actual insertion of needle catheter assembly (47) into shaft (44), there is naturally no disclosure concerning a bevel at the end of a catheter or needle or any concern for the orientation of the (non-existing) bevel.

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Furthermore, although Cunningham arguably discloses the use of a "pseudo skin," which would be belt (108) of skin traction mechanism (36), this pseudo skin does not include an opening for receiving the catheter and needle, as required by claim 1 on appeal. See FIG. 7 of Cunningham. As is clear from FIG. 3 of Cunningham, skin traction mechanism (36) is attached to case (32) of Cunningham's device, whereas catheter needle assembly (47) extends from within case (32) but not through the pseudo skin (belt 108) of the skin traction mechanism.

In summary, Cunningham does not disclose a bevel, Cunningham does not disclose a sensor for sensing the orientation of a bevel, and Cunningham does not disclose a pseudo skin having an opening for receiving a catheter and a needle.

The examiner agrees that Cunningham does not teach of a bevel, an orientation of the bevel, and the pseudo skin having an opening for receiving the catheter and needle for the reasons that Cunningham is silent toward these teachings, not because of any correlation between the bevel of the needle and insertion of the needle catheter assembly into the shaft as argued by the appellant.

The appellant alleges on page 15, lines 4-14 that the examiner erred in combining the teachings of Grayzel to Cunningham as the two are not analogous art.

In response to applicant's argument that Cunningham and Grayzel is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Grayzel is in the same field of endeavor as Cunningham for insertion of catheter/needle and it also provides features that is pertinent to sensing the orientation of the bevel. Grayzel and Cunningham both teach of methods for effective insertion of needle/catheter, therefore the same field of endeavor.

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Additionally Grayzel teaches a method of facilitating the insertion of catheter with a beveled tip with indication markings for participant to easily identify the orientation of the bevel before, during and after the insertion. One of ordinary skill in the art would recognize that the indication markings would readily indicate the orientation of the bevel during insertion, therefore Grayzel is reasonably pertinent to the particular problem with which the applicant is concerned. For at least the reasons above, Cunningham and Grayzel are analogous art and it would have been obvious to combine the teachings of Grayzel and Cunningham in teaching sensing an orientation of the bevel.

The appellant further alleges on page 15, starting from line 15 that the prior art do not teach of sensing an orientation of the bevel. The appellant specifically asserts that Rosenberg fails to disclose sensing the orientation of the bevel by teaching away from having a bevel (page 15, lines 22-30). Specifically citing Rosenberg in teaching of removing the cutting edges (bevel) of the catheter.

The examiner respectfully disagrees with the assertion that Rosenberg teaches away from having a bevel. The examiner notes that Rosenberg removes the sharp edge purely for the safety of the person and any potential damage to the property. The appellant is taking the citation of Rosenberg out of context in making the assertion that it teaches away from having a bevel. Rosenberg recites:

“Catheter and central line are commercially available from sources such as Target Therapeutics of Fremont, California, USA and U.S. Surgical of Connecticut, USA. Preferably, the catheter is modified such that the end of the tool (such as any cutting edges) are removed,

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leaving only the handle and the shaft. The end of the catheter tool is not required for the virtual reality simulation, and is removed to prevent any potential damage to persons or property” (col 5, lines 6-11).

Based upon this complete citation, it appears that Rosenberg is merely stating an opinion relating to the safety of the participant and the equipment. Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). “A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use.” In re Gurley, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994). Given this, the preferred method of Rosenberg are insufficient to disqualify it as prior art for its teaching of the orientation of the bevel of the needle / catheter in combination with Cunningham, nor would it discourage one of ordinary skill in the art from considering the orientation of the bevel of a needle / catheter in relation to the correct placement of the needle / catheter with Cunningham, where the placement of the needle is measured based on the pitch, yaw and translation. Rosenberg additionally teaches of sensing the rotational motion of the catheter / needle. One of ordinary skill in the art would automatically correlate the rotation of the catheter to the orientation of the bevel, as when the catheter is rotated, the orientation of the bevel is rotated along with it. Therefore one of ordinary skill in the art would undoubtedly recognize the correlation between the orientation of the bevel and the rotational motion of the catheter. And therefore one of ordinary skill in the art would have combined the teachings of Rosenberg and Cunningham in providing an orientation of the bevel in assessing the correct placement of the needle / catheter in the simulation.

The appellant argues on page 16, that Rosenberg is only concerned with the tracking of the movement of the shaft portion within the patient, and not concerned about the insertion portion of the procedure. Again, the examiner disagrees with the argument as the examiner failed to find any limitation in claim 1 pertaining to the insertion of the needle/catheter. The appellant has not made any ties between the insertion and extraction of the needle / catheter and the sensor for sensing the orientation of the bevel in claim 1. The appellant's argument amounts to a general allegation that the claim defines a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the reference. As such the examiner maintains that it would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Rosenberg and Cunningham in providing an orientation of the bevel in assessing the correct placement of the needle/catheter in the simulation.

Lastly, the appellant re-emphasized the assertion that Rosenberg does not disclose of a bevel or means for monitoring the orientation of a bevel vis-à-vis a patient's skin during catheter/needle insertion. The examiner respectfully disagrees, as explained above Rosenberg does not teach away from having a bevel. Additionally the limitation of monitoring the orientation of a bevel vis-à-vis a patient's skin during a catheter/needle insertion is not found in the limitations of claim 1 and therefore amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the reference.

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(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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Examiner, Art Unit 3715

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